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LAHRSOW=1

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EXAMINER

MCCLAIN-COLEMAN, TYNESHA L.

ART UNIT

PAPER NUMBER

1784

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,151	Applicant(s) LAHRSOW, JOBST	
	Examiner TYNESHA MCCLAIN-COLEMAN	Art Unit 1784	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/14/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 13-20, 25-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 13-20, 25-33 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The after-final amendment filed on May 14, 2010 is entered and acknowledged. Claims 11, 13-20, 25-33, and 35 are pending in the application. Claims 1-10, 12, 21-24, and 34 are cancelled.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 11, 13-14, 16, 20, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Digiulio* GB 1516525 (hereinafter "*Digiulio*") in view of *Herreid* US 6016862 (hereinafter "*Herreid*").

5. With respect to claims 11, 14, 16, 20, and 25, *Digiulio* discloses an oral composition comprising 0.01% to 5% (0.1 g/kg to 50 g/kg) by weight of water-soluble calcium salt and 0.01% to 5% (0.1 g/kg to 50 g/kg) by weight of water-soluble phosphate salt (page 2, lines 52-58). Phosphoric acid may be used as the phosphate salt portion of the oral composition (page 2, lines 42-46).

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6. However, *Digiulio* does not disclose the oral composition comprises 2.3 g/kg to 7.0 g/kg (50 to 150 mMol/kg) of a calcium source and 1.4 g/kg to 48 g/kg (15 to 500 mMol/kg) of phosphoric acid.

7. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use any amount of calcium salt and phosphoric acid within the range disclosed by *Digiulio*.

8. One having ordinary skill in the art would have been motivated to do this because the range disclosed by *Digiulio* overlaps the range claimed by the applicant. Therefore, it would have been obvious to use any amount of calcium salt and phosphoric acid within the range disclosed by *Digiulio*, including 2.3 g/kg to 7.0 g/kg of a calcium source and 1.4 g/kg to 48 g/kg of phosphoric acid as claimed by the applicant, with the expectation of successfully preparing an oral composition used to remineralize dental enamel.

9. *Digiulio* also does not disclose a method of preparing the oral composition.

10. *Herreid* discloses preparing a gummi candy by mixing sugar, corn syrup, and water. This mixture is cooked to 240°F with stirring and cooled to 200°F.

Gelatin/sorbitol crumbles are added to the hot sugar mixture with stirring. This mixture forms a clear solution. A mixture of water, citric acid (fruit acid, claims 14 and 16), red coloring, and strawberry flavor (claim 25) is added to the clear solution. The finished gummi candy was poured onto a sheet dusted with corn starch, allowed to cool, and cut into shapes (column 9, lines 25-55).

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11. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare the oral composition disclosed by *Digiulio* using the method disclosed by *Herreid*.

12. One having ordinary skill in the art would have been motivated to do this because *Digiulio* teaches the oral compositions are any product that is retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces (page 2, lines 4-6). Therefore, it would have been obvious to prepare the oral composition disclosed by *Digiulio* using any method of preparing a chewable mass, including the method of preparing a gummi candy as disclosed by *Herreid*, with the expectation of successfully preparing an oral composition used to remineralize dental enamel.

13. It would have also been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the gummi candy of *Digiulio* in view of *Herreid* to be transparent.

14. One having ordinary skill in the art would have been motivated to do this because *Herreid* teaches the prepared gummi candy has typical color (column 9, line 56), and it is well known in the art that colored gummi candy typically have a transparent appearance. Also, the desired color of the gummi candy is contingent upon the coloring agent or dye used, if any, as it is well known in the art to prepare colorless/clear gummi candy (*Herreid*: column 9, line 51). In addition to this, *Digiulio* teaches when the oral compositions are applied to the mouth, the calcium and phosphate ions diffuse into the enamel to precipitate as calcium phosphate in order to remineralize the tooth enamel (page 2, lines 88-105). The precipitates may be white in color (page 3, lines 80-81).

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Since the colored precipitate is not formed until the oral composition is placed in the mouth and the oral compositions can be stored for long periods of time prior to use (page 1, lines 63-68), it is expected that the calcium salt and phosphorous acid would not form a precipitate during the production of the gummi candy.

15. Further, it would have been obvious to optimize all ingredients are stirred to form a homogenous product during the preparation of the gummi candy.

16. One having ordinary skill in the art would have been motivated to do this because the calcium salt and phosphoric acid would be evenly distributed throughout the oral composition in order to ensure the remineralization of tooth enamel with the precipitate formed upon mastication.

17. Regarding claims 13, 14, and 16, *Digiulio* discloses the desired pH can be obtained by incorporating into the oral compositions common acidifying agents such as citric acid and malic acid (page 2, lines 115-119; and page 5, lines 67-80). In addition to this, it is well known in the art to blend multiple acids in order to obtain a desired taste for the oral composition.

18. Claims 13-15, 17-18, 26-31, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Digiulio* GB 1516525 (hereinafter "*Digiulio*") in view of *Herreid* US 6016862 (hereinafter "*Herreid*") as applied to claim 11 above, in further view of *Hirose et al.* US 20030039706 (hereinafter "*Hirose*").

19. With respect to claims 13-15, 17-18, 26-31, 33, and 35, *Digiulio* in view of *Herreid* discloses using acids such as citric acid and malic acid (claims 27, 28, and 30) to

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prepare a strawberry flavored (claim 35) transparent and homogenous (claim 33) gummi candy (*Digiulio*: page 2, lines 115-119; and page 5, lines 67-80. *Herreid*: column 9, lines 52-53 and 56).

20. However, *Digiulio* in view of *Herreid* does not disclose using a carboxylic acid such as lactic acid (claims 14-15 and 28-29) to prepare the gummi candy. *Digiulio* in view of *Herreid* also does not disclose preparing an aqueous solution of at least one acidifying agent by adding a first calcium-complexing acid such as pyruvic acid followed by adding a more powerful calcium-complexing agent such as citric acid or malic acid (claims 17, 18, 26, and 31).

21. *Hirose* discloses incorporating an organic acid into candy (paragraphs [0094] and [0115]). Organic acids such as citric acid, malic acid, lactic acid (claims 14-15 and 28-29), and pyruvic acid (claims 16 and 30) may be used (paragraph [0095]).

22. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate the organic acids disclosed by *Hirose* into the method of preparing a gummi candy product disclosed by *Digiulio* in view of *Herreid*.

23. One having ordinary skill in the art would have been motivated to do this because *Digiulio* teaches it is necessary to obtain the proper pH by incorporating common acidifying agents in order to allow the calcium ions and phosphate ions to coexist in solution in the mouth (i.e. without immediately precipitating) (page 2, lines 73-80 and 115-119). In addition to this, *Hirose* teaches the organic acid can be used to control the pH in the mouth by promoting the secretion of saliva (paragraph [0096]). Therefore, it would have been obvious, given the teaching of *Hirose*, to incorporate organic acids

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such as lactic acid and pyruvic acid into the method of making gummi candy disclosed by *Digiulio* in view of *Herreid* with the expectation of successfully preparing an oral composition that has a proper pH and is used to remineralize tooth enamel.

24. In addition to this, it would have also been obvious to a person of ordinary skill in the art at the time the invention was made to use various acidifying agents in any order, including adding pyruvic acid first followed by citric acid or malic acid (claims 13, 17-18, 26-27, and 31).

25. One having ordinary skill in the art would have been motivated to do this because it is well known in the art that the desired taste of the gummi candy product is obtained by blending multiple acids in any order, including adding pyruvic acid first followed by citric acid or malic acid as claimed by the applicant. Therefore, it would have been obvious to use various acidifying agents in any order, including adding pyruvic acid first followed by citric acid or malic acid, in method of making gummi candy disclosed by *Digiulio* in view of *Herreid* and *Hirose* with the expectation of successfully preparing an oral composition with a desired taste that has a proper pH and is used to remineralize tooth enamel. Further, given that *Digiulio* in view of *Herreid* and *Hirose* discloses a method of preparing a gummi candy using acids that are identical to those used in the present invention, it is clear that the method of *Digiulio* in view of *Herreid* and *Hirose* would intrinsically result in the addition of a first-calcium complexing acid (pyruvic acid) and another calcium complexing acid (citric acid or malic acid).

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26. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Digiulio* GB 1516525 (hereinafter "*Digiulio*") in view of *Herreid* US 6016862 (hereinafter "*Herreid*") as applied to claim 11 above, in further view of *Chow et al.* US 20010033831 (hereinafter "*Chow*").

27. Regarding claim 19, *Digiulio* in view of *Herreid* does not disclose the calcium salt is at least one of calcium oxide, calcium hydroxide, and calcium carbonate.

28. *Chow* discloses candies and confectioneries that are formulated to release calcium and phosphate ions into the mouth of a human patient in order to remineralize teeth (Abstract and paragraph [0010]). Calcium ion-releasing compounds such as $\text{Ca}(\text{OH})_2$, CaO , and combinations and mixtures thereof may be used (paragraph [0026]).

29. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the water soluble calcium salt disclosed by *Digiulio* with the calcium ion-releasing compounds disclosed by *Chow*.

30. One having ordinary skill in the art would have been motivated to do this because *Digiulio* teaches calcium salts used to make the oral composition have a solubility of at least 0.07% (page 2, lines 29-31), and *Chow* teaches a similar calcium ion-releasing compound with a solubility greater than about 0.1% and less than about 10% (paragraph [0026]). Based upon the fact that both *Digiulio* and *Chow* similarly teach oral compositions comprising a calcium source and a phosphate ion source, it would have been obvious, given the teachings of *Chow*, to substitute the water soluble calcium

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salt disclosed by *Digiulio* with $\text{Ca}(\text{OH})_2$ and/or CaO with the expectation of successfully preparing an oral composition used to remineralize tooth enamel.

31. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Digiulio* GB 1516525 (hereinafter "*Digiulio*") in view of *Herreid* US 6016862 (hereinafter "*Herreid*") and *Hirose et al.* US 20030039706 (hereinafter "*Hirose*") as applied to claim 26 above, in further view of *Chow et al.* US 20010033831 (hereinafter "*Chow*").

32. With respect to claim 19, *Digiulio* in view of *Herreid* and *Hirose* does not disclose the calcium salt is at least one of calcium oxide, calcium hydroxide, and calcium carbonate.

33. *Chow* discloses candies and confectioneries that are formulated to release calcium and phosphate ions into the mouth of a human patient in order to remineralize teeth (Abstract and paragraph [0010]). Calcium ion-releasing compounds such as $\text{Ca}(\text{OH})_2$, CaO , and combinations and mixtures thereof may be used (paragraph [0026]).

34. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the water soluble calcium salt disclosed by *Digiulio* with the calcium ion-releasing compounds disclosed by *Chow*.

35. One having ordinary skill in the art would have been motivated to do this because *Digiulio* teaches calcium salts used to make the oral composition have a solubility of at least 0.07% (page 2, lines 29-31), and *Chow* teaches a similar calcium ion-releasing compound with a solubility greater than about 0.1% and less than about 10%

(paragraph [0026]). Based upon the fact that both *Digiulio* and *Chow* similarly teach oral compositions comprising a calcium source and a phosphate ion source, it would have been obvious, given the teachings of *Chow*, to substitute the water soluble calcium salt disclosed by *Digiulio* with $\text{Ca}(\text{OH})_2$ and/or CaO with the expectation of successfully preparing an oral composition used to remineralize tooth enamel.

Response to Arguments

36. Applicant's arguments, filed May 14, 2010, with respect to the rejection(s) of claim(s) 11, 13-17, 19, 20, 24-30, and 32-35 over *Maeda* in view of *Lederman* (see pages 7-11) and claims 18 and 31 over *Maeda* in view of *Lederman* and *Yang* (see pages 11-13) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over *Digiulio* GB 1516525 (hereinafter "*Digiulio*") in view of *Herreid* US 6016862 (hereinafter "*Herreid*"), *Hirose et al.* US 20030039706 (hereinafter "*Hirose*"), and *Chow et al.* US 20010033831 (hereinafter "*Chow*"). As disclosed above, *Digiulio* in view of *Herreid*, *Hirose*, and *Chow* disclose a method of preparing a transparent/colorless and homogenous gummi candy for remineralization of tooth enamel that is similar to the method claimed by the applicant.

Conclusion

37. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reference *Wiedemann* CA 2138780 teaches a gelatin based

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chewable mass and chewable sweet used to remineralize tooth enamel comprising calcium and phosphate ions, which is similar to the gummi candy taught by *Digiulio* in view of *Herreid*, *Hirose*, and *Chow* as described above.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TYNESHA MCCLAIN-COLEMAN whose telephone number is (571)270-1153. The examiner can normally be reached on Monday - Thursday 7:30AM - 5:00PM Eastern Time.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on (571)272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TYNESHA L MCCLAIN-COLEMAN/
Examiner, Art Unit 1784

/Jennifer C. McNeil/
Supervisory Patent Examiner, Art Unit 1784